

# EXHIBIT O

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
<u>Ex Rel</u>	)	
VEN-A-CARE OF THE	)	CIVIL ACTION NO. 00 CV 10698
FLORIDA KEYS, INC.,	)	MEL
a Florida Corporation,	)	
by and through its principal	)	
officers and directors,	)	
ZACHARY T. BENTLEY and	)	
T. MARK JONES,	)	
	)	
Plaintiff,	)	
v.	)	
	)	
ABBOTT LABORATORIES, INC.,	)	
	)	
Defendant.	)	
	)	

**COMPLAINT FOR VIOLATIONS OF  
THE FALSE CLAIMS ACT, 31 U.S.C. §3729, et seq.  
AGAINST ABBOTT LABORATORIES, INC.**

VEN-A-CARE OF THE FLORIDA KEYS INC. ("VEN-A-CARE" or the "Relator") brings this fraud action on behalf of the United States and on the Relator's own behalf, against ABBOTT LABORATORIES, INC. ("Abbott") to recover losses sustained by the Medicaid Program arising out of the DEFENDANT'S violations of the Federal False Claims Act ("False Claims Act" or the "Act") 31 U.S.C., §§3729-3732. Over the course of several years, Abbott reported inflated pharmaceutical prices that it knew Medicaid relied upon to set reimbursement rates for Abbott's pharmaceutical products. Abbott's actual sales prices, the prices generally and currently available in the marketplace, for its pharmaceutical products were far less than the prices reported by Abbott. By

CIVIL ACTION NO. 00 CV 10698 MEL

knowingly reporting inflated prices - often two times higher than prices generally and currently available in the marketplace - Abbott ensured its customers received inflated reimbursement and profits from Medicaid. Abbott then used the public fisc as a marketing tool, actively promoting government-funded "spreads" between (1) its fraudulently inflated prices and (2) its actual sales prices as an inducement to its customers. These efforts allowed Abbott to increase its profits by boosting sales for its drugs.

### **I. NATURE OF ACTION**

1. Ven-A-Care brings this action on behalf of the United States to recover treble damages and civil penalties under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and to recover damages and other monetary relief.

2. Ven-A-Care bases its claims on Abbott having submitted and caused the submission of false or fraudulent claims to the United States in violation of 31 U.S.C. §3729(a)(1), and having made and used false statements to get false or fraudulent claims paid by the United States in violation of 31 U.S.C. § 3729(a)(2).

3. Within the time frames detailed below, Abbott engaged in a fraudulent scheme that caused the Medicaid Program to pay excessive reimbursement to Abbott's customers; e.g., pharmacies, physicians, hospitals, home health agencies, nursing homes, home infusion companies, clinics and physicians (hereafter referred to collectively as "Customers"). In furtherance of this scheme, Abbott reported false, fraudulent and inflated drug prices for certain drugs (listed in paragraph 33 below) to several price reporting compendia that the Medicaid Program relied upon to set

CIVIL ACTION NO. 00 CV 10698 MEL

reimbursement rates for Abbott's customers. A chart setting out examples showing the difference between the prices at which Abbott actually sold its drugs and the false prices reported by Abbott is attached hereto as **Exhibit A**. Abbott knew that the Medicaid Program relied on Abbott's reported prices to the pricing compendia to set reimbursement rates for claims submitted for Abbott's drugs. Abbott then sold the drugs for far lower prices, and marketed to existing and potential Customers the government-funded "spread" between the inflated reimbursement amounts and the actual acquisition costs of the drugs to boost its sales and profits.

4. Abbott knew that its false price reporting and marketing efforts would cause its Customers to submit claims for fraudulently inflated Medicaid reimbursement.

5. Abbott's fraudulent scheme to induce Customers to purchase its products by ensuring that Medicaid reimbursement rates for those products would be set at artificially inflated levels violated the FCA, the federal anti-kickback statute, 42 U.S.C. §1320a-7b(b) and numerous state laws.

6. To get fraudulent claims paid by the Medicaid Program, Abbott also routinely made false statements by reporting these same fraudulently inflated prices directly to the states. These statements violated the FCA and various state laws.

## II. JURISDICTION

7. Jurisdiction is founded upon the Federal False Claims Act, 31 U.S.C. §3729-32, specifically 31 U.S.C. §3730, and also 28 U.S.C. §§1331, 1345.

CIVIL ACTION NO. 00 CV 10698 MEL

8. Ven-A-Care's claims against Abbott in this matter were filed on February 15, 2001 in the District of Massachusetts.<sup>1</sup> The claims against Abbott were severed from the main action in anticipation of the United States' declination and in anticipation of the Relator litigating those declined claims. After severance, the Relator filed this Amended Severed Complaint pursuant to the Court's Order dated July 31, 2007.

9. The Court has subject matter jurisdiction to entertain this action under 28 U.S.C. §§ 1331 and 1345. The Court may exercise personal jurisdiction over Abbott pursuant to 31 U.S.C. §3732(a) because Abbott resides or transacts business in the District of Massachusetts.

10. The Relator has standing to bring and has brought this action on behalf of itself and the United States pursuant to 31 U.S.C. §3730.

### III. VENUE

11. Venue is proper in the District of Massachusetts under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Abbott resides or transacts business in this District.

### IV. PARTIES

12. Relator Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care"), is a corporation organized under the laws of Florida, with its principal offices in Key West, Florida. Ven-A-Care's principal officers and directors during the relevant time period

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<sup>1</sup>This case originated in the District of Massachusetts as Case No.00-CV-10698, the *qui tam* matter filed by Ven-A-Care under seal in front of United States District Judge Lasker.

CIVIL ACTION NO. 00 CV 10698 MEL

have included John M. Lockwood, M.D., Zachary Bentley, Luis Cobo and T. Mark Jones, who are each citizens of the United States and reside in Key West, Florida. Ven-A-Care is a pharmacy licensed to provide the prescription drugs specified in this Complaint and has been, during the relevant period of this Complaint, a Medicare and Florida Medicaid provider.

13. The FCA, 31 U.S.C. § 3730(b)(1), provides that private parties may bring a lawsuit on behalf of the United States to recover damages for false claims.

Ven-A-Care brought this action against Abbott on behalf of itself and the United States.

14. The Relator, Ven-a-Care became aware of Abbott's false claim scheme alleged herein due to its position as an industry insider. The Relator commenced its *qui tam* action against Abbott for the drugs at issue based upon its industry insider information. Ven-A-Care, as a pharmacy, has access to pricing information such as wholesaler and GPO catalogues and computer programs revealing the prices generally and currently available in the marketplace, but not known to the general public or the Government. Ven-A-Care, as an industry insider, discovered that Abbott created huge profit spreads on the Drugs at issue and that the Drugs were reimbursed by Medicaid at amounts that substantially, and in some cases, exceeded two or three times the cost of the drug. Ven-A-Care's principals were aware that Medicaid reimbursed for drugs at amounts that were intended to be based on an estimation of cost and not provide for huge windfall profits at the Government's expense.

15. The United States has declined to join the prosecution of this action, but remains a party to this action pursuant to 31 U.S.C. § 3730(c)(3). The United States

CIVIL ACTION NO. 00 CV 10698 MEL

has requested that it be supplied with copies of all pleadings filed in the action and copies of all deposition transcripts.

16. Defendant Abbott is a corporation organized under the laws of Illinois with its principal offices in Abbott Park, Illinois. At all times material to this civil action, Abbott has transacted business throughout the United States, selling and distributing its drugs, including but not limited to those identified in this Complaint, to purchasers within this District.

## V. THE LAW

### A. The False Claims Act

17. The FCA provides in pertinent part, that:

- (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government

\* \* \*

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

\* \* \*

- (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

CIVIL ACTION NO. 00 CV 10698 MEL

18. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted to \$5,500 to \$11,000 for violations occurring on or after September 29, 1999.

**B. The Federal Anti-Kickback Statute**

19. Congress first enacted the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), in 1972 to protect the integrity of Medicare and Medicaid. Congress strengthened the statute in 1977, and again in 1987, to ensure that kickbacks masquerading as legitimate transactions would not evade its reach. See Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-fraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

20. The anti-kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally funded medical items, including items provided under Medicare and Medicaid. In pertinent part, the statute provides:

(b) Illegal remuneration

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind-

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or



CIVIL ACTION NO. 00 CV 10698 MEL

service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). Those who violate the statute also are subject to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of up to \$50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

## **VI. THE MEDICAID PROGRAM**

### **A. THE PROGRAM**

21. Medicaid was created to provide access to healthcare for elderly, indigent or disabled residents of the United States.

22. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled.

### **B. FUNDING**

23. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

24. The Medicaid programs of all states reimburse for prescription drugs.

25. The United States Government, under the Secretary of the United States Department of Health and Human Service, is required to pay to each state, for each calendar quarter, an amount equal to the Federal Medical Assistance Percentage ("FMAP") of the total amount expended by the state during the quarter as medical assistance under the state Medicaid plan pursuant to 42 U.S.C. § 1396b(a)(1).

26. The federal portion of States' Medicaid payments, Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. The federal portion consists of a minimum of 50% up to a maximum of 83%. For example, Florida's FMAP contributed by the United States in the fiscal year October 1, 2003 to September 30, 2004 was 58.93%.

CIVIL ACTION NO. 00 CV 10698 MEL

27. The Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

28. Each State Health Plan must, in part, provide a formula for payment of reimbursement claims for prescription drugs, and each state's plan must be approved by the Secretary of HHS. The formula determines the reimbursement amount the state plan will pay for each drug manufactured by each manufacturer whose prescription drugs qualify for Medicaid reimbursement, based upon an estimation of the provider's acquisition cost plus a reasonable dispensing fee. 42 CFR §447.331. Under certain circumstances, the federal Center for Medicare and Medicaid Services ("CMS") may establish a "Federal Upper Limit," binding on all state plans, on the allowable reimbursement for a particular drug.

29. The states' methodologies for arriving at a provider's Estimated Acquisition Cost ("EAC") for each covered drug, as required by 42 CFR §447.331, must be approved by the Secretary of HHS.

30. The vast majority of states award contracts to private companies to evaluate and process Medicaid recipients' claims for payment. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid program, which in turn obtains federal funds from the United States.

31. To claim its FMAP payment, each state must submit a report to the United States Secretary of Health and Human Services reflecting its anticipated Medicaid expenses for the quarter. The Secretary is required to estimate the state's FMAP

CIVIL ACTION NO. 00 CV 10698 MEL

entitlement for the quarter, based on the state's report and such other investigation as the Secretary may find necessary, and pay that amount to the state in such installments as the Secretary may determine, adjusted for any overpayments or underpayments in prior quarters. 42 U.S.C. § 1396b(d)(1), (2A). The Secretary's determination of a state's FMAP entitlement obligates any appropriations available for payments to the state. 42 U.S.C. § 1396b(d)(4).

32. Abbott knowingly reported false, inflated price and cost data for the specified drugs to the pharmaceutical pricing compendia relied on by the states, or directly to the states, or both, and therefore caused claims submitted by each state to officers and employees of the UNITED STATES for FMAP to be greater than they would have been but for the DEFENDANTS' false price representations. As a result, Abbott caused the United States to expend FMAPs in amounts greater than would have been expended, but for the Defendants' false reports of price and cost data, and thus caused injury to the federal fisc.

**C. DRUG REIMBURSEMENT**

33. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-97, requires pharmaceutical companies to submit to the Food and Drug Administration ("FDA") a listing of every drug product in commercial distribution. 21 U.S.C. § 355. The FDA provides for the assignment to each listed drug product of a unique 11-digit, 3-segment number, known as the National Drug Code ("NDC"). FDA has assigned approximately 170,000 NDCs to drug products. The drugs and corresponding NDCs at issue in this case (collectively referred as the "Drugs") are listed below:

CIVIL ACTION NO. 00 CV 10698 MEL

1	Erythromycin Ethylsuccinate Tab 400 mg	00074-2589-13
2	Erythromycin Ethylsuccinate Tab 400 mg	00074-2589-53
3	ERYTHR ETH LIQ 200mg/5ml	00074-3747-16
4	ERYTHR ETH LIQ 400mg/5ml	0007-43748-16
5	E.E.S. 400 FILM	00074-5729-11
6	E.E.S. 400 FILM	00074-5729-13
7	E.E.S. 400 FILM	00074-5729-19
8	E.E.S. 400 FILM	00074-5729-53
9	ERYTHR BSE TAB 500mg	00074-6227-13
10	ERYTHROMYC DR 250mg CAP	00074-6301-13
11	ERYTHROMYC DR 250mg CAP	00074-6301-53
12	Ery-tab E/c Ud 250 Mg 100's	00074-6304-11
13	Ery-tab E/c 250 Mg 100's	00074-6304-13
14	Ery-tab E/c 250 Mg 30's	00074-6304-30
15	ERY-TAB 250MG E	00074-6304-40
16	ERY-TAB 250MG E	00074-6304-53
17	EES 200 Susp. 100ml	00074-6306-13
18	EES 200 Liq 200 Mg/5 ml	00074-6306-16
19	Erythromycin Stearate 500 Mg Tab 100's	00074-6316-13
20	Ery-tab 333 mg	00074-6320-11
21	Ery-tab 333 mg	00074-6320-13
22	Ery-tab 333 mg	00074-6320-30
23	Ery-tab 333 mg	00074-6320-53
24	Ery-tab 500 Mg u	00074-6321-11
25	Ery-tab 500 Mg e	00074-6321-13
26	ERYTHR BSE TB 250mg	00074-6326-11
27	Erythromycin Base 250 Mg Tab 100's	00074-6326-13
28	Erythromycin Base 250 Mg Tab 500's	00074-6326-53
29	ERYTHR STE 250mg TAB	00074-6346-19
30	Erythromycin Stearate 250 Mg Tab 100's	00074-6346-20
31	Erythromycin Stearate Ud 250 Mg Tab 100's	00074-6346-38
32	ERYTHR STE 250mg TAB	00074-6346-41
33	Erythromycin Stearate 250 Mg Tab 500's	00074-6346-53
34	E.E.S. GRAN 200	00074-6369-02
35	E.E.S. GRAN 200	00074-6369-10
36	E.E.S. 400 LIQ	00074-6373-13
37	EES 400 Liq 400 Mg/5 ml	00074-6373-16
38	EES/sulfisoxazole 200 Mg, 100 ml	00074-7156-13
39	EES/sulfisoxazole 200 Mg 150 ml	00074-7156-43
40	EES/sulfisoxazole 200 Mg 200 ml	00074-7156-53
41	Pediazole Susp	00074-8030-13
42	Pediazole Susp	00074-8030-43

CIVIL ACTION NO. 00 CV 10698 MEL

43 Pediazole Susp

00074-8030-53

34. Drug manufacturers, such as Abbott, have not typically submitted claims for reimbursement to federal health care programs. Instead, Abbott marketed its products to its Customers, who then purchased the products either directly or through wholesalers based on a price the Customers negotiated with Abbott. In addition to using wholesalers, Customers also purchased Abbott products through group purchasing organizations ("GPO"), who negotiated prices on behalf of Abbott's Customers.

35. Abbott's Customers submitted claims for payment for Abbott products to Medicaid after dispensing or administering Abbott drugs.

36. For the most part, in the Medicaid program, claims submitted by retail pharmacies are processed and tracked using the NDC of the drug.

37. Each of the claims at issue is a false claim, in part, because each was supported by, and the reimbursement amount was determined from, the false and misleading price information provided by Abbott in connection with the Drugs. The claims at issue in this action are all claims for reimbursement submitted to Medicaid by or on behalf of Providers that sought and received payments in excessive amounts because of Abbott's false price reports. The claims at issue number in the tens of thousands and were submitted by thousands of Providers nationwide throughout the relevant time period of the Complaint. Each claim is in the possession of the state Medicaid programs.

38. During the relevant period, Abbott usually reported prices to various price

CIVIL ACTION NO. 00 CV 10698 MEL

publishers and services on an annual basis. The price publishers used the information to publish pricing compendia.

39. The reimbursement amounts for claims submitted by Abbott's Customers for the drugs at issue in this Complaint were directly influenced by Abbott's false price representations. The information contained in the published pricing compendia was used by most third party payor insurance companies, including the Medicare and Medicaid programs, in determining the reimbursement rates for prescription drugs. Abbott knew of the impact of its price representations on government reimbursement on claims submitted by its Customers for its drugs.

40. No governmental payor knew of or sanctioned Abbott's conduct as set forth in this Complaint; i.e., its deliberate manipulation of its published prices for certain of its products to induce its Customers to purchase those products.

**D. REIMBURSEMENT FORMULAS**

41. When reimbursing for drugs, the Medicaid Program's goal has been to pay an amount which, in the aggregate, reflects the lower of (1) the estimated acquisition cost ("EAC") of covered drugs, plus a reasonable dispensing fee, or (2) a provider's usual and customary charges to the general public. To determine the EAC for a covered drug, State Medicaid programs are required to develop reimbursement formulas that must be approved by the Secretary of HHS. 42 C.F.R. §§ 447.331, 447.332, and 447.333 (2005).

42. While the specific reimbursement formulas vary from state to state, the various State Medicaid programs have generally reimbursed for each drug based on



CIVIL ACTION NO. 00 CV 10698 MEL

the lowest of (a) the EAC as set by the states, (b) the maximum allowable cost ("MAC") set by the state Pharmaceutical Reimbursement Boards, or (c) the providers' usual and customary charge. For multiple source drugs subject to a federal upper limit, states must in the aggregate not pay more than those limits. 42 C.F.R. §§ 447.331, 447.332 and 447.333 (2005).

43. The states' methodology for arriving at EAC includes:

- A. discounting a percentage off of the Average Wholesale Price ("AWP");
- B. adding a percentage to the Wholesale Acquisition Cost ("WAC"); and/or,
- C. requiring the drug companies to certify prices directly in writing to the Medicaid program.

44. AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail Customer who then dispenses or administers it to a patient. WAC is used to refer to the price at which a pharmaceutical firm typically sells a drug to wholesalers who would then resell it to a retail Customer.

42. While the majority of states use published AWP's to calculate reimbursement, approximately six states (Alabama, Florida, Maryland, Massachusetts, Rhode Island and Texas) have used the wholesale acquisition cost ("WAC") to set the EAC.

45. The AWP's and WAC's relied upon by the State Medicaid programs have generally been those published by (1) Thomson Publishing, publisher of the Red Book



CIVIL ACTION NO. 00 CV 10698 MEL

and various other price publications, (2) First Databank, publisher of the Blue Book and other electronic price publications; or (3) Medi-Span, Inc.<sup>2</sup>, publisher of an electronic or automated price service and the Hospital Formulary Pricing Guide. Thomson Publishing, First Databank and Medi-Span, Inc. are hereafter referred to as the "Publishers" and their various publications and data services are hereinafter referred to as "Price Publications."

46. In addition to relying on the manufacturers' reported prices as published in the Price Publications, some State Medicaid programs also received price representations directly from manufacturers, and relied on these representations to confirm the accuracy of the figures they use to determine state reimbursement amounts. For example, the State of Texas required drug companies to submit their prices directly to the Texas Medicaid program in a signed certification attesting to the accuracy of the price information.

**E. DRUG WHOLESALERS' ROLE**

47. The majority of Abbott's drugs, including the Drugs specified in this Complaint, are distributed through drug wholesalers who resell and distribute the drugs to hospitals, pharmacies, physicians and clinics.

48. Three companies, Mckesson Drug, Cardinal and Amerisource Bergen have comprised an overwhelming majority of the U.S. wholesale drug market during the relevant time period. Wholesalers generally sell to any health care provider(such as

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<sup>2</sup>Any variance between the prices reported by the companies First Databank and Medi-Span is minimal.

CIVIL ACTION NO. 00 CV 10698 MEL

pharmacies, physicians and clinics) who can lawfully dispense or administer prescription drugs.

## VII. ABBOTT'S SCHEME

49. From at least on or before January 1, 1994, and continuing through the present, Abbott defrauded the United States by knowingly causing the Medicaid Program to pay false or fraudulent claims for various drugs including but not limited to forms of Erythromycin.<sup>3</sup>

50. The specific Drug products at issue herein are identified by NDC number in ¶¶33 above and are hereinafter referred to jointly as the "Drugs."

51. Abbott marketed and sold its products, including the Drugs, to Customers. The Customers purchased the products either directly from Abbott, through a GPO contract or through wholesalers.

52. The amount paid by a Customer was typically based on a price negotiated with Abbott or the GPO.

53. Abbott offered "contract pricing" to many of its customers that was less than "non-contract" or "Regular Cost" prices generally offered by wholesalers to any customer. Attached as **Exhibit B** is a print out from the Econolink software program for the wholesaler McKesson showing the AWP, Regular Cost and Contract Price. Exhibit

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<sup>3</sup> Erythromycin is an oral antibiotic drug and is used to treat many different types of infections. Pediazole is a combination of Erythromycin and Sulfisoxazole which is used to treat ear infections in children. It also may be used for other purposes. E.E.S., or Erythromycin Ethylsuccinate, is used for treatment of infections and may be used for the prevention of heart infections.

CIVIL ACTION NO. 00 CV 10698 MEL

B shows a "Contract Price" for Ery-Tab 250 MG which is less than the "Regular Cost." Abbott created inflated spreads on all the Drugs at issue for customers that purchased the drugs at Regular Cost, available to virtually any industry customer, and an even greater spread for those purchasing the Drugs "under contract".

54. Regardless of the method of purchase, Abbott's Customers submitted claims for payment to Medicaid when an Abbott product was dispensed to a program beneficiary. The claims submitted by Abbott's Customers were paid at amounts directly influenced by Abbott's false and fraudulent prices.

55. Abbott routinely disseminated false pricing information for the Drugs to the Pricing Publications. Abbott employees typically reported the false and fraudulent prices to the Pricing Publications annually, although they sometimes did so more often. On most occasions, Abbott reported inflated "List Prices" or "Direct Prices" (both referred to hereinafter as LP), WACs and/or AWP. A LP is supposed to reflect the price paid by a Customer that buys drugs directly from Abbott and not through a wholesaler.

56. Abbott knew that the prices it reported to the pricing compendia, including both WAC and LP, controlled the pricing compendia's report of AWP. To the extent that Abbott reported WACs for the Drugs, Abbott knew that the WAC prices it reported controlled the pricing compendia's report of WAC. Furthermore, Abbott, in some instances, verified the pricing compendia's reports of WAC, LP and AWP.

57. With extremely few exceptions, Abbott reported increasingly higher prices for the Drugs from at least on or before January 1, 1994 through the present. At the

CIVIL ACTION NO. 00 CV 10698 MEL

same time, the prices Abbott actually charged to its Customers, the prices generally and currently available in the marketplace, decreased or remained the same.

58. Abbott knew that the prices it reported to the Price Publications directly affected reimbursement amounts paid by the Medicaid Program. The false or fraudulent prices Abbott reported to the Price Publications caused inflated government reimbursement amounts on claims submitted by Abbott's Customers for the Drugs. Attached as **Exhibit A** is a chart setting out some examples for each NDC at issue showing: reported prices (AWP and WAC), Relator Cost and the corresponding spreads(difference between the prices at which Abbott actually sold its drugs and the false prices reported by Abbott). The prices listed as those available to the Relator, as a small volume infusion pharmacy, are some of the highest prices offered by Abbott in the marketplace. Therefore, the inflated spreads available to the Relator were some of the lowest spreads in the marketplace.

59. Abbott manipulated its LPs, AWP's and WAC's to induce its Customers to purchase Abbott's products, including the Drugs, by marketing to its Customers the huge profits that would result. Abbott actively used the inflated spreads and huge profits as a marketing tool directed at providers to promote increased sales of the Drugs. The spreads, in effect, marketed themselves. Any purchaser could easily calculate the potential profit using the reported prices and the actual sales price. For example, the inflated spreads were readily apparent from information on Econolink software programs available from the wholesaler McKesson. See **Exhibit B**.

60. Abbott was well aware of how Medicaid used Abbott's reported pricing information to set reimbursement levels to providers for Abbott products.

61. The Medicaid programs did not know of or sanction Abbott's conduct as set forth in this Complaint; i.e., the deliberate manipulation of its published prices to create inflated reimbursement spreads that would induce its Customers to purchase the Drugs. Abbott never disclosed to the Medicaid programs its false price reporting practices.

62. Abbott's scheme to defraud the United States by causing inflated reimbursements for the Drugs ran from at least 1995 through the present. Over that time period, Medicaid paid in excess of \$144 Million for the Drugs at issue (identified by 43 NDC numbers).

63. During that time period, Abbott reported increasingly higher LPs, WACs and AWP for the Drugs to the Price Publications while the actual contract prices at which Abbott sold the Drugs to its Customers decreased or remained the same.

64. For example, Abbott's false and fraudulent price reporting on its ERY-TAB 333MG, NDC 00074-6320-13, represents how Abbott reported false and fraudulent prices. **Exhibit C** shows the following for ERY-TAB 333MG: the reported AWP and WAC prices; the "Wholesaler List Price to Relator" otherwise known as the "Regular Cost" or non-contract cost; the "Contract Price to Relator"; and the corresponding dollar and percentage spreads created by Abbott's false price reports.

65. In 1994, the published AWP for Abbott's ERY-TAB 333MG was \$34.97. By 1996, Abbott reported false prices that drove the AWP for ERY-TAB 333MG to

CIVIL ACTION NO. 00 CV 10698 MEL

\$35.98. By 2004, Abbott reported false prices that drove the AWP to \$38.88. At the same time, the price at which Abbott's ERY-TAB 333MG was widely available to purchasers such as the Relator remained the same or decreased. The price for Abbott's ERY-TAB 333MG available to the Relator in 1994 was \$12.82 and the price available for Abbott's ERY-TAB 333MG to the Relator in 2005 was \$11.55; the difference (and potential profit) between the reported price and the actual selling price for ERY-TAB 333MG was as great as \$27.33 a dose, or more than two times the actual price at which Abbott sold ERY-TAB 333MG to Customers such as the Relator.

66. Likewise, the WAC for Abbott's ERY-TAB 333 MG also increased while the prices Abbott charged its customers for the drug decreased. The WAC for ERY-TAB 333 MG rose from \$29.45 in 1994 to \$31.10 in 2005.

67. Abbott's false and fraudulent price reporting on ERY-TAB 250MG, NDC 00074-6304-13, is another example of Abbott's manipulation of the spread. **Exhibit D** shows the following for Abbott's ERY-TAB 250MG: the reported AWP and WAC prices; the "Wholesaler List Price to Relator" otherwise known as the "Regular Cost" or non-contract cost; the "Contract Price to Relator"; and the corresponding dollar and percentage spreads created by Abbott's false price reports. In 1994, Abbott caused the AWP to be published as \$23.75, but by 2005 the AWP had risen to \$26.41. The price to the Relator, however, decreased over that same time period from \$7.50 in 1994 to \$6.60 in 2005; the difference (and potential profit) between the reported price and the actual selling price for ERY-TAB 250MG was as great as \$19.81 a dose, or more than two times the actual price at which Abbott sold ERY-TAB 250MG.

CIVIL ACTION NO. 00 CV 10698 MEL

68. Likewise the WAC for ERY-TAB 250 MG also increased from \$19.00 in 1994 to \$21.13 in 2005.

69. Abbott fully controlled and manipulated the WACs, DPs, LPs and AWP for the Drugs to boost its sales at the expense of third party payors, including Medicaid.

70. Between at least 1994 and through the present, Abbott knowingly manipulated its reported prices for the entire list of Drugs specified in paragraph 33 to create inflated spreads and knowingly marketed those inflated spreads to induce Customers to purchase the Drugs.

#### **FIRST CAUSE OF ACTION**

(False Claims Act: Presentation of False Claims)  
(31 U.S.C. § 3729(a)(1))

71. Plaintiff repeats and realleges ¶¶ 1 through 70 as fully set forth herein.

72. Abbott knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States for the Drugs for reimbursement that were substantially higher than providers' actual acquisition costs for the Drugs and based on reported prices that were fraudulently and artificially manipulated by Abbott. Abbott knowingly used the spread as an unlawful inducement in violation of the federal anti-kickback statute, causing resulting false and fraudulent claims to be submitted.

73. By virtue of the false or fraudulent claims that Abbott caused to be made, the United States has suffered damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than \$5,000 and up to \$10,000 for each violation occurring before September 29, 1999, and

CIVIL ACTION NO. 00 CV 10698 MEL

not less than \$5,500 and up to \$11,000 for each violation occurring on or after September 29, 1999.

**SECOND CAUSE OF ACTION**

(False Claims Act: Making or Using False  
Records or Statements to Cause Claims to be Paid)  
(31 U.S.C. § 3729(a)(2))

74. Plaintiff repeats and realleges ¶¶ 1 through 70 as if fully set forth herein.

75. Abbott knowingly made, used, or caused to be made or used, false records or statements to cause false or fraudulent claims to be paid or approved by the United States.

76. By virtue of the false records or false statements made by Abbott, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than \$5,000 and up to \$10,000 for each violation occurring before September 29, 1999, and not less than \$5,500 and up to \$11,000 for each violation occurring on or after September 29, 1999.

**PRAYER FOR RELIEF**

WHEREFORE, the Plaintiff, on behalf of the United States, demands and prays that judgment be entered in its favor against Abbott, jointly and severally, as follows:

1. On the First and Second Causes of Action, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.



CIVIL ACTION NO. 00 CV 10698 MEL

2. The Relator requests that it receive an award from the proceeds of the action pursuant to 31 U.S.C. § 3730(d) including a percentage of the proceeds of the action, and reasonable expenses necessarily incurred, plus reasonable attorneys' fees and costs.

**DEMAND FOR JURY TRIAL**

The Relator, on behalf of the United States, demands a jury trial in this case.

Respectfully Submitted,  
Attorneys for Plaintiff,  
Ven-A-Care of the Florida Keys, Inc.

/s/ Jonathan Shapiro  
Jonathan Shapiro  
BBO No. 454220  
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CIVIL ACTION NO. 00 CV 10698 MEL

GOODE, CASSEB, JONES,  
RIKLIN, CHOATE & WATSON  
John E. Clark  
2122 North Main Avenue  
San Antonio, Texas 78212-9680  
Phone: 210-733-6030

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 30<sup>th</sup> day of August, 2007, I caused a copy of this Complaint to be delivered to George B. Henderson, II, Assistant U.S. Attorney, United States Courthouse, 1 Courthouse Way, Suite 9200, Boston, MA 02210 and Laurie Oberembt, Trial Attorney and Gejaa T. Gobena, Trial Attorney, U.S. Department of Justice, Civil Division, Commercial Litigation Branch, Fraud Section, P. O. Box 261, Ben Franklin Station, Washington, DC 20044.

/s/ Jonathan Shapiro  
Jonathan Shapiro

Drug/Dosage	NDC	Year	First Databank AWP	MediSpan WAC	Price to Relator	AWP \$ Spread	AWP % Spread	WAC \$ Spread	WAC % Spread
ERYTHROMYCIN ES 400 MG TAB	00074-2589-13	2001	\$23.24	\$18.59	\$10.72	\$12.52	216.7910448	\$7.87	173.4141791
ERYTHROMYCIN ES 400 MG TAB	00074-2589-53	2001	\$110.38	\$88.30	\$52.00	\$58.38	212.2692308	\$36.30	169.8076923
ERYTHROMYCIN 200 MG/5 ML SUSP	00074-3747-16	2001	\$20.76	\$16.62	\$7.82	\$12.94	265.4731458	\$8.80	212.5319693
ERYTHROMYCIN 400 MG/5 ML SUSP	0007-43748-16	2001	\$38.67	\$30.94	\$16.97	\$21.70	227.8727166	\$13.97	182.3217443
E.E.S. 400 FILMTAB	00074-5729-13	2001	\$23.24	\$18.59	\$14.37	\$8.87	161.7258177	\$4.22	129.3667363
E.E.S. 400 FILMTAB	00074-5729-19	2001	\$205.52	\$164.42	\$135.03	\$70.49	152.2032141	\$29.39	121.7655336
E.E.S. 400 FILMTAB	00074-5729-53	2001	\$110.38	\$88.30	\$69.67	\$40.71	158.4326109	\$18.63	126.7403474
ERYTHROMYCIN 500 MG FILMTAB	00074-6227-13	2001	\$27.15	\$21.72	\$13.55	\$13.60	200.3690037	\$8.17	160.295203
ERYTHROMYCIN 250 MG CAP EC	00074-6301-13	2001	\$25.77	\$20.62	\$10.27	\$15.50	250.9250243	\$10.35	200.7789679
ERYTHROMYCIN 250 MG CAP EC	00074-6301-53	2001	\$124.98	\$99.99	\$48.68	\$76.30	256.73788	\$51.31	205.4026294
ERY-TAB 250 MG TABLET EC	00074-6304-11	2001	\$27.55	\$23.20	\$9.90	\$17.65	278.2828283	\$13.30	234.3434343
ERY-TAB 250 MG TABLET EC	00074-6304-13	2001	\$25.18	\$20.14	\$7.21	\$17.97	349.2371706	\$12.93	279.334258
ERY-TAB 250MG TABLET EC	00074-6304-30	2001	\$7.55	\$6.36	\$2.76	\$4.79	273.5507246	\$3.60	230.4347826
ERY-TAB 250MG TABLET EC	00074-6304-40	2001	\$10.07	\$8.48	\$3.67	\$6.40	274.386921	\$4.81	231.0626703
ERY-TAB 250 MG TABLET EC	00074-6304-53	2001	\$119.58	\$95.67	\$34.93	\$84.65	342.3418265	\$60.74	273.8906384
E.E.S. 200 MG/5 ML SUSPENSION	00074-6306-16	2001	\$20.76	\$16.62	\$12.67	\$8.09	163.851618	\$3.95	131.1760063
ERYTHROCIN 500 MG FILMTAB	00074-6316-13	2001	\$26.35	\$21.08	\$13.30	\$13.05	198.1203008	\$7.78	158.4962406
ERY-TAB 333 MG TABLET EC	00074-6320-11	2001	\$39.44	\$33.21	\$15.37	\$24.07	256.6037736	\$17.84	216.0702668
ERY-TAB 333 MG TABLET EC	00074-6320-13	2001	\$37.06	\$29.65	\$11.66	\$25.40	317.838765	\$17.99	254.2881647
ERY-TAB 333MG TABLET EC	00074-6320-30	2001	\$12.35	\$9.88	\$4.35	\$8.00	283.908046	\$5.53	227.1264368
ERY-TAB 333 MG TABLET EC	00074-6320-53	2001	\$176.05	\$140.84	\$56.57	\$119.48	311.2073537	\$84.27	248.965883
ERY-TAB 500 MG TABLET EC	00074-6321-11	2001	\$44.88	\$37.79	\$19.31	\$25.57	232.418436	\$18.48	195.701709
ERY-TAB 500 MG TABLET EC	00074-6321-13	2001	\$42.50	\$33.01	\$16.74	\$25.76	253.8829152	\$16.27	197.1923536
ERYTHROMYCIN 250 MG FILMTAB	00074-6326-11	2001	\$19.53	\$16.45	\$9.66	\$9.87	202.173913	\$6.79	170.2898551
ERYTHROMYCIN 250 MG FILMTAB	00074-6326-13	2001	\$14.78	\$11.83	\$6.79	\$7.99	217.6730486	\$5.04	174.2268041
ERYTHROMYCIN 250 MG FILMTAB	00074-6326-53	2001	\$70.24	\$56.19	\$32.99	\$37.25	212.9130039	\$23.20	170.3243407
ERYTHROCIN 250 MG FILMTAB	00074-6346-19	2001	\$134.42	\$107.54	\$64.32	\$70.10	208.9863184	\$43.22	167.1952736
ERYTHROCIN 250 MG FILMTAB	00074-6346-20	2001	\$14.58	\$11.67	\$6.83	\$7.75	213.4699854	\$4.84	170.863836
ERYTHROCIN 250 MG FILMTAB	00074-6346-38	2001	\$16.96	\$14.28	\$10.03	\$6.93	169.0927218	\$4.25	142.3728814
ERYTHROCIN 250 MG FILMTAB	00074-6346-41	2001	\$6.14	\$4.91	\$3.31	\$2.83	185.4984894	\$1.60	148.3383686
ERYTHROCIN 250 MG FILMTAB	00074-6346-53	2001	\$69.29	\$55.43	\$33.20	\$36.09	208.7048193	\$22.23	166.9578313
E.E.S. 400 MG/5 ML SUSPENSION	00074-6373-16	2001	\$38.67	\$30.94	\$21.58	\$17.09	179.1936979	\$9.36	143.373494
ERYTHROMYCIN/SULFISOX SUSP	00074-7156-13	2001	\$12.77	\$10.21	\$4.21	\$8.56	303.3254157	\$6.00	242.5178147
ERYTHROMYCIN/SULFISOX SUSP	00074-7156-43	2001	\$18.88	\$15.11	\$6.32	\$12.56	298.7341772	\$8.79	239.0822785
ERYTHROMYCIN/SULFISOX SUSP	00074-7156-53	2001	\$24.82	\$19.86	\$8.42	\$16.40	294.7743468	\$11.44	235.8669834
PEDIAZOLE ORAL SUSPENSION	00074-8030-13	2001	\$17.75	\$14.20	\$10.51	\$7.24	168.8867745	\$3.69	135.1094196
PEDIAZOLE ORAL SUSPENSION	00074-8030-43	2001	\$26.37	\$21.10	\$15.57	\$10.80	169.3641618	\$5.53	135.5170199
PEDIAZOLE ORAL SUSPENSION	00074-8030-53	2001	\$34.63	\$27.70	\$20.40	\$14.23	169.754902	\$7.30	135.7843137

EXHIBIT "A"

08/09/01

M c K e s s o n

ECONOLINK System

15:54

Facility: VENA CARE

Range: From - 00074-6304-13

Selected By: NDC Code

Thru - 00074-6304-13

Sorted By: NDC Code

Description: ERY-TAB 250MG E/C 100

Economost #: 1932102

Subst Econo #:

Local #:

Local Dept:

Generic: 40730 ERYTHROMYCIN BASE

Mica Dept: AD

Therapeutic: 081212 MACROLIDES

Form: TABLET DR

NDC: 00074-6304-13

Mfg Unit: TAB

UPC: 3-00746-30413

Strength: 250MG

Mfg Name: ABBOTT LABORATORIES

Sched: 6

Alt Source:

Std Ord Min: 001

Alternate ID:

Size: 100.00

AWP: \$26.50

Order Unit: EA

AWP Last Updt: 08/09/01

Case Qty: 00048

REG Price: \$7.72

Qual Qty: 0

Price CD:

Start Date: 00/00/00

End Date: 00/00/00

Last Update: 04/20/00

CNTR/SPCL Price: \$7.21

Qual Qty: 1

Price CD: E

Start Date: 07/01/01

End Date: 10/31/01

Last Update: 08/09/01

Retail Price: .00

Reg Code:

Retail Type:

Reg Price:

Rtl Base Cost: .00

A.W.P.:

National Cost: .00

Profit %: .00

Sugg Retail: .00

Label Cnt:

Zone Cust:

Last Maint: 00/00/00

Reorder Quantity:

Source Supply: 0000

Reorder Point: .00

Inventory Cnts: .000

ABC Velocity Ind:

Physical Loc:

EXHIBIT "B"

08/09/01 M c K e s s o n ECONOLINK System

15:54 Facility: VENA CARE

Range: From - 00074-6320-13

Selected By: NDC Code

Thru - 00074-6320-13

Sorted By: NDC Code

Description: ERY-TAB 333MG E/C 100

Economost #: 1150804

Subst Econo #:

Local #:

Local Dept:

Generic: 40731 ERYTHROMYCIN BASE

Mica Dept: AD

Therapeutic: 081212 MACROLIDES

Form: TABLET DR

NDC: 00074-6320-13

Mfg Unit: TAB

UPC: 3-00746-32013

Strength: 333MG

Mfg Name: ABBOTT LABORATORIES

Sched: 6

Alt Source:

Std Ord Min: 001

Alternate ID:

Size: 100.00

AWP: \$39.01

Order Unit: EA

AWP Last Updt: 08/09/01

Case Qty: 00048

REG Price: \$13.20

Qual Qty: 0

Price CD:

" Start Date: 00/00/00

End Date: 00/00/00

Last Update: 04/20/00

CNTR/SPCL Price: \$11.66

Qual Qty: 1

Price CD: E

" Start Date: 07/01/01

End Date: 10/31/01

Last Update: 08/09/01

Retail Price: .00

Reg Code:

Retail Type:

Reg Price:

Rtl Base Cost: .00

A.W.P.:

National Cost: .00

Profit %: .00

Sugg Retail: .00

Label Cnt:

Zone Cust:

Last Maint: 00/00/00

Reorder Quantity:

Source Supply: 0000

Reorder Point: .00

Inventory Cnts: .000

ABC Velocity Ind:

Physical Loc:

EXHIBIT "B"

Drug/Dosage	NDC	Year	First Databank AWP	MediSpan WAC	Wholesaler List Price to Relator	Contract Price to Relator	AWP \$ Spread	AWP % Spread	WAC \$ Spread	WAC % Spread
ERY-TAB 333 MG TABLET EC	00074-6320-13	1994	\$34.97	\$29.45	\$12.82		\$22.15	272.7769111	\$16.63	229.7191888
ERY-TAB 333 MG TABLET EC	00074-6320-13	1995	\$34.97	\$29.45	\$12.82		\$22.15	272.7769111	\$16.63	229.7191888
ERY-TAB 333 MG TABLET EC	00074-6320-13	1996	\$35.98	\$28.79	\$12.82		\$23.16	280.6552262	\$15.97	224.5709828
ERY-TAB 333 MG TABLET EC	00074-6320-13	1997	\$35.98	\$28.79	\$13.20		\$22.78	272.5757576	\$15.59	218.1060606
ERY-TAB 333 MG TABLET EC	00074-6320-13	1998	\$35.98	\$28.79	\$13.20		\$22.78	272.5757576	\$15.59	218.1060606
ERY-TAB 333 MG TABLET EC	00074-6320-13	1999	\$37.06	\$29.65	\$13.20		\$23.86	280.7575758	\$16.45	224.6212121
ERY-TAB 333 MG TABLET EC	00074-6320-13	2000	\$37.06	\$29.65	\$13.20		\$23.86	280.7575758	\$16.45	224.6212121
ERY-TAB 333 MG TABLET EC	00074-6320-13	2001	\$37.06	\$29.65		\$11.66	\$25.40	317.838765	\$17.99	254.2881647
ERY-TAB 333 MG TABLET EC	00074-6320-13	2002	\$37.06	\$29.65		\$11.66	\$25.40	317.838765	\$17.99	254.2881647
ERY-TAB 333 MG TABLET EC	00074-6320-13	2003	\$37.06	\$29.65	\$13.20		\$23.86	280.7575758	\$16.45	224.6212121
ERY-TAB 333 MG TABLET EC	00074-6320-13	2004	\$38.88	\$31.10		\$11.55	\$27.33	336.6233766	\$19.55	269.2640693
ERY-TAB 333 MG TABLET EC	00074-6320-13	2005	\$38.88	\$31.10		\$11.55	\$27.33	336.6233766	\$19.55	269.2640693

EXHIBIT "C"

Drug/Dosage	NDC	Year	First Databank AWP	MediSpan WAC	Wholesaler List Price to Relator	Contract Price to Relator	AWP \$ Spread	AWP % Spread	WAC \$ Spread	WAC % Spread
ERY-TAB 250 MG TABLET EC	00074-6304-13	1994	\$23.75	\$19.00	\$7.50		\$16.25	316.6667	\$11.50	253.33333
ERY-TAB 250 MG TABLET EC	00074-6304-13	1995	\$23.75	\$19.00	\$7.50		\$16.25	316.6667	\$11.50	253.33333
ERY-TAB 250 MG TABLET EC	00074-6304-13	1996	\$24.44	\$19.55	\$7.50		\$16.94	325.8667	\$12.05	260.66667
ERY-TAB 250 MG TABLET EC	00074-6304-13	1997	\$24.44	\$19.55	\$7.72		\$16.72	316.5803	\$11.83	253.23834
ERY-TAB 250 MG TABLET EC	00074-6304-13	1998	\$24.44	\$19.55	\$7.72		\$16.72	316.5803	\$11.83	253.23834
ERY-TAB 250 MG TABLET EC	00074-6304-13	1999	\$25.18	\$20.14	\$7.72		\$17.46	326.1658	\$12.42	260.88083
ERY-TAB 250 MG TABLET EC	00074-6304-13	2000	\$25.18	\$20.14	\$7.72		\$17.46	326.1658	\$12.42	260.88083
ERY-TAB 250 MG TABLET EC	00074-6304-13	2001	\$25.18	\$20.14		\$7.21	\$17.97	349.2372	\$12.93	279.33426
ERY-TAB 250 MG TABLET EC	00074-6304-13	2002	\$25.18	\$20.14		\$7.21	\$17.97	349.2372	\$12.93	279.33426
ERY-TAB 250 MG TABLET EC	00074-6304-13	2003	\$25.18	\$20.14	\$7.47		\$17.71	337.0817	\$12.67	269.61178
ERY-TAB 250 MG TABLET EC	00074-6304-13	2004	\$26.41	\$21.13		\$6.60	\$19.81	400.1515	\$14.53	320.15152
ERY-TAB 250 MG TABLET EC	00074-6304-13	2005	\$26.41	\$21.13		\$6.60	\$19.81	400.1515	\$14.53	320.15152

EXHIBIT "D"